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Registration Decision RD2011-12

Liquid Corn Gluten

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Registration Decision for Liquid Corn Gluten

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Liquid Corn Gluten Manufacturing Concentrate and TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer, containing the active ingredient Liquid Corn Gluten Manufacturing Concentrate, as a pre-emergent dandelion, crabgrass (smooth and large) and white clover seed germination inhibitor for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-03, *Liquid Corn Gluten.* This Registration Decision[2] describes this stage of the PMRA's regulatory process for liquid corn gluten and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2011-03, *Liquid Corn Gluten.*

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2011-03, *Liquid Corn Gluten* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Liquid Corn Gluten?

Liquid corn gluten is the active ingredient contained in the end-use product TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer at a concentration of 99.81%. Liquid corn gluten is a water soluble material that is derived from corn gluten meal through enzyme hydrolysis. TurfMaize Liquid Bio-herbicide Corn Gluten Weed Preventer is a pre-emergent dandelion, crabgrass (smooth and large) and white clover seed germination inhibitor for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass species.

Health Considerations

Can Approved Uses of Liquid Corn Gluten Affect Human Health?

Potential exposure to liquid corn gluten may occur when handling and applying the end-use product or when people enter a recently treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The active ingredient, liquid corn gluten, is expected to be of low acute toxicity via the oral, dermal and pulmonary routes, minimally irritating to the skin, mildly irritating to the eyes, and a potential sensitizer. Therefore, precautionary statements alerting users to the eye irritation and sensitization potential of liquid corn gluten are required on the labels for Liquid Corn Gluten Manufacturing Concentrate and TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer.

Limited toxicology information was available for liquid corn gluten. However, information available on corn gluten meal, which is the starting material for processing liquid corn gluten, did not indicate hazards that would be expected with liquid corn gluten.

The data requirements for acute toxicity, short-term toxicity, irritation and sensitization potential, prenatal developmental toxicity and genotoxicity studies were waived by the PMRA based on toxicological information on the starting material of corn gluten meal, widespread use in the food industry of the hydrolyzation enzyme used in the manufacture of liquid corn gluten, as well as the existing food and cosmetic uses of hydrolyzed corn gluten without any reported adverse effects.

Risk to humans from domestic use of TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is not expected to be of concern due to the low toxicity of the formulation and additional precautionary measures on the label that are aimed at mitigating exposure, including restrictions on re-entry to treatment sites and the wearing of personal protective equipment (PPE).

Residues in Water and Food

Dietary risks from liquid corn gluten on food and water are not of concern.

TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is for herbicidal use on domestic lawns, and is not intended for use on food crops.

No risk due to exposure from drinking water is anticipated as liquid corn gluten, by its organic nature, is expected to degrade rapidly in the environment and is not likely to be persistent.

Risks From Handling Liquid Corn Gluten

Risks are not of concern when liquid corn gluten is used according to label directions, which include protective measures.

Residential exposure to individuals mixing, loading, or applying TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is not expected to result in unacceptable risk when the product is used according to label directions.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible if the precautionary label statements are observed by the domestic users.

Precautionary (for example, wearing of personal protective equipment) and general hygiene statements on the label of TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer are considered adequate to protect individuals, children and pets from domestic use of this product.

Environmental Considerations

What Happens When Liquid Corn Gluten Is Introduced Into the Environment?

Liquid corn gluten is an hydrolyzate of corn gluten meal, a naturally occurring substance in the environment. The use of liquid corn gluten is not expected to cause any adverse environmental effects to non-target organisms.

As the protein in liquid corn gluten is already partially broken down, it is expected that further degradation of liquid corn gluten will occur in the environment. Given the known history of use of corn gluten meal and the limited exposure expected from residential turf use, the risk to non-target organisms from liquid corn gluten in the end-use product TurfMaize Bio-Herbicide Corn Gluten Weed Preventer is considered to be negligible, and the use of this end-use product is not expected to cause any adverse effects to the environment.

Value Considerations

What Is the Value of TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer?

TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer contains liquid corn gluten at a concentration of 99.81%. TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer is a water soluble material containing an active ingredient that is derived from an active ingredient present in the registered corn gluten meal products. It is a non-conventional herbicide for use on lawns where established perennial ryegrass and Kentucky bluegrass are the predominant grass species. TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer may inhibit dandelion, crabgrass (smooth and large) and white clover seed germination when used in conjunction with a sound lawn maintenance program.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures on the technical and end-use product labels to address the potential risks identified in this assessment are as follows:

> The signal words "POTENTIAL SENSITIZER" and "CAUTION EYE IRRITANT" and the statement "May cause sensitization" are present on the principal and the secondary display panels, respectively, on the labels for Liquid Corn Gluten Manufacturing Concentrate and TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer.

Both the technical and end-use product labels include additional precautionary statements, including "Avoid contact with skin, eyes or clothing," "May irritate eyes and skin," "May cause sensitization," and "May cause respiratory irritation." Also, the labels include the precautionary statements "Avoid breathing vapours" and "Avoid breathing spray mist" on the technical and the end-use product labels, respectively.

The TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer label also instructs users to not apply the end-use product if a member of the household has a sensitivity or allergy to corn, and not to apply under windy conditions.

As a general hygiene measure, the TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer label requires users wear a long-sleeved shirt, long pants, closed foot wear and gloves when handling the end-use product and during application. Also, the label instructs users to avoid contact of the product with the skin, eyes or clothing. As a further hygiene measure, freshly prepared spray solution is to be used each time when using a hand-held or back pack sprayer.

To prevent post-application exposure of adults, children and pets, the TurfMaize Liquid Bio-Herbicide Corn Gluten Weed Preventer label includes the restricted-entry statement, "Do not re-enter or allow re-entry of adults, children or pets into treated areas until the spray is dried."

Environment

No additional risk mitigation measures or label statements were required.

Other Information

1. The relevant test data on which the decision is based (as referenced in PRD2011-03 — *Liquid Corn Gluten)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1. **Comments on efficacy of corn gluten products in general, description of efficacy claims, efficacy trials, and contraindication of use of the product with a fertilizer containing nitrogen were received and assessed with the following response:**

Comments: Based on consultations with major stakeholders, it was suggested that weed control via inhibition with corn gluten was not successful. Specific complaints for similar products containing corn gluten included unacceptable product performance, the complexity of the directions and possible user error in following the directions for use and whether efficacy trials performed in Western Canada were used in the registration process. The commenter suggested that the timing of application appeared to be very critical and the residual period is limited to days rather than weeks; so it is important that that the label be clear on the limitations associated with use. The commenter indicated that the difference between the terms 'control', 'inhibition' and 'suppression' should be clearly communicated to users so they understand the efficacy claims.

The commenter also suggested that, because corn gluten is an effective fertilizer, it may only be contributing nutrients towards a healthier turf to out-compete weed growth. It was also suggested that the label should be more pronounced in recognizing that the product is primarily a fertilizer in nature and should not be applied in addition to other nitrogen-based fertilizers.

Response:

A variety of pest control claims may appear on the label of a product that is registered in Canada under the *Pest Control Products Act*. For conventional herbicide products, the typical performance standards such as control and suppression are defined in DIR2003-04, *Efficacy Guidelines for Plant Protection Products*. For non-conventional products, the PMRA recognizes that some products, such as those based on corn gluten, may not be as efficacious as conventional products to support a control or suppression performance claim, and may warrant a lesser claim. The proposed Guidelines for the Registration of Non-Conventional Pest Control Products (PRO2010-06) provides examples of lower level of performance claims such as "reduces damage, reduces annoyance, reduces inoculum, reduces populations, suppresses symptoms or may inhibit" that may be considered.

All performance claims must be substantiated by information reviewed during the registration process. Sometimes there may be a number of factors or conditions that may impact a product's performance (both conventional and non-conventional). In this case, those conditions appear on the product label. Given the range of performance claims available, and the factors that may impact product performance, it is important that users of pest control products read the label to understand what level of control the product may provide, and any conditions that need to be met in order for it to be realized.

In regards to efficacy trials, none of the trials were conducted in Western Canada. However, the PMRA does not require trials to be conducted in all geographic regions of Canada, particularly for non-conventional products.

In the case of corn gluten-based pest control products, the control claim is that the product may inhibit seed germination of certain turf weeds when used in conjunction with a sound lawn maintenance program. Additional conditions and restrictions that should be observed in order for this level of control to be realized, including a contraindication of use with a fertilizer containing nitrogen, are included in the directions for use section of the product label.

It should also be noted that corn gluten-based products have dual properties. That is to say that they possess both pesticidal and fertilizer properties. The use of these products as pesticides is regulated by the PMRA under the *Pest Control Products Act*, while their use as fertilizers is regulated by the Canadian Food Inspection Agency under the *Fertilizers Act*.